DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

July 16, 2001

WARNING LETTER NO. 2001-NOL-37

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Harry D. Simmons, Jr., President
Simmons Farm Raised Catfish, Inc.
2628 Erickson Road
Yazoo City, Mississippi 39194

Dear Mr. Simmons:

We inspected your firm, located at 2628 Erickson Road, Yazoo City, Mississippi on April 17 and 18, 2001, and found that you have serious deviations from the Seafood HACCP regulations Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your fresh frozen catfish products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth. You can find this Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations were as follows:

- You must retain records at the processing facility for at least two years after the date they were prepared to comply with 21 CFR 123.9(b)(1). However, your firm's Catfish Producer Certification forms and Live Fish Producer HACCP Visit forms for aquacultured catfish were not retained prior to November 1, 2000. This deviation was previously brought to your attention on the Form FDA 483 dated May 17, 1999.

- You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for aquacultured catfish lists a monitoring procedure and frequency at the receiving critical control point that is not adequate to control aquaculture drugs, and environmental chemical and pesticide contamination. The presence of a certificate needs to be monitored for each shipment.

During the inspection, our investigator documented numerous insanitary conditions that also cause the product you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act. The inspection found that employees working in direct contact with food and food-contact surfaces

did not take necessary precautions to protect against contamination of those items with microorganisms or foreign substances. For example:

(1) Employees were observed standing on the live fish conveyor belt and shelf of the deheader, which were not washed or sanitized before use;
(2) An employee wiped water condensate from the ceiling and cooling unit above the fish chill tank with a squeegee blade. The water dripped from the ceiling and cooling unit into the fish chill tank and shelf of the deheader and neither the chill tank nor the shelf were washed or sanitized prior to use;
(3) Employees routinely removed catfish products, including fillets, from the floor, rinsed them with water, and returned them to the production lines;
(4) An employee was observed allowing his unsanitized forearms and elbows to contact breaded catfish fillets; and,
(5) Employees placed sanitized containers, used to hold catfish products, directly on the wet floor, without washing or sanitizing the containers.

In addition, our investigator documented conditions that facilitate unsanitary operations, which are associated with the construction and design of your facility. For example:

- water condensate dripped from the ceiling and overhead cooler units onto catfish processing equipment, which was not washed or sanitized prior to use;
- no hand washing facilities inside the processing areas or break room (This deviation was previously brought to your attention on the Form FDA 483 dated May 17, 1999); and,
- plastic curtains contacted employee's footwear and ice used on the catfish fillets. The curtains were not washed or sanitized.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan, Catfish Producer Certification forms, and Live Fish Producer HACCP Visit forms or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504)253-4519.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: FDA Form 483